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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,390	07/24/2003	Robert H. Wham	2155 CIP 2 A	9811

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UNITED STATES SURGICAL,
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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,390	WHAM ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 28-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 28-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments, filed with the response of May 5, 2006, have been fully considered by the examiner. The following is a complete response to the May 5, 2006 communication.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 16-18, 28-40 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller, III (5,836,943).

Miller discloses an electrosurgical system and method of treating tissue that comprises a controller for controlling the output pulses of the generator in response to measured tissue characteristics. In particular, Miller specifically teaches that impedance and/or rate of change of impedance is used to control the output of the generator in a method for treating tissue (col. 6, lines 13-61). As disclosed at column 12, lines 64 through column 13, line 10, tissue impedance is measured between pulses, and the generator is then regulated to control subsequent output pulses of the generator. Output pulses are controlled by varying the duty cycle and the magnitude of the output voltage (col. 10, lines 11-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 15, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller, III ('943) in view of the teaching of Yates et al (5,558,671).

As addressed above, Miller discloses a system and method for controlling output pulses of a generator for coagulating (i.e. sealing) tissue by monitoring tissue impedance after a pulse (i.e. between pulses) and using the measured impedance to control subsequent pulses. Miller does not disclose the use of a look-up table as the means to arrive at the values for the subsequent pulses.

Yates et al disclose another tissue sealing device that relies on impedance feedback to control the output of an RF generator. In particular, Yates et al disclose various algorithms for controlling future application of energy based on the sensed impedance including using a look-up table to determine future energy applications (col. 8, lines 8-22).

To have provided the Miller, III system with a look-up table as a means to determine output levels for a generator in response to sensed tissue impedance would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Yates et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 28-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-52 of U.S. Patent No. 6,398,779. Although the conflicting claims are not identical, they are not patentably distinct from each other because the step of "keeping constant or varying RF energy parameters" in the instant claims is deemed to be substantially analogous and obvious with respect to the step of simply "varying RF energy parameters" as set forth in the patented claims.

Response to Arguments

Applicant's arguments filed May 5, 2006 have been fully considered but they are not persuasive.

With regard to the Miller reference, applicant asserts that Miller provide "impedance feedback monitoring" and that applicant's claims do not rely exclusively on impedance feedback monitoring. It is noted that applicant's claim 1 recites "varying RF parameters of individual pulses of subsequent RF energy pulses in accordance with at

least one characteristic of an electrical transient that occurs during the individual RF energy pulses". Claims 5 and 6 specifically state that the electrical transient is selected from the group consisting of electrical current transient and tissue impedance. Hence, the applicant's claims would clearly read on an impedance feedback system that alters the RF energy parameters of subsequent pulses in accordance with sensed tissue impedance that occurs during previous pulses. This is exactly what the Miller reference does. See columns 12 and 13 where Miller expressly states that impedance (i.e. a characteristic of an electrical transient) is measured between pulses (i.e. to monitor the transient that occurred during the individual RF pulse) and controls the output of the generator (i.e. varies or keeps constant the output) in accordance with the monitored transient. Applicant has not addressed any differences in the applicant's claimed invention and the Miller reference other than to state that the language of claim 1 is not "impedance feedback monitoring". The examiner maintains that the Miller reference discloses a system that operates within the limitations set forth in the rejected claims.

With regard to the obviousness rejection, applicant again continues to assert that neither the Miller reference nor the Yates et al reference disclose the step of delivering RF pulses in response to electrical transients of previous pulses. As asserted above, the examiner maintains that the Miller reference is doing precisely that. Again, applicant's own specification and claims specifically indicate that measured tissue impedance may be the electrical transient that is monitored to control the subsequent pulses. Yates is merely cited to show that it is known to use a look-up table to provide

the corresponding generator output to a measured tissue impedance as recited in claims 14, 15, 41 and 42.

Finally, applicant has indicated that a terminal disclaimer has been provided to obviate the double patenting rejection. However, no such terminal disclaimer appears in the response of May 5, 2006, nor does the transmittal letter indicate that such a paper has been filed. Accordingly, the rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
June 14, 2006